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ScienceDirect
Research in Social and Administrative Pharmacy ■ (2014) ■–■
RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

Original Research

Consolidating innovative practice models: The case for obstructive sleep apnea services in Australian pharmacies

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Abstract

Background: Pharmacists in Australia have pioneered an innovative role in providing obstructive sleep apnea (OSA) services in community pharmacies. A professional practice framework is yet to be established for this novel service area.
Objectives: To explore the practices and experiences of Australian pharmacy staff providing OSA services.
Method: Semi-structured telephone interviews were conducted using an interview guide to explore *a priori* areas of interest. Interviews were audio recorded, transcribed verbatim and thematically analyzed using a framework approach.
Results: Interviews were completed with 22 practitioners from demographically diverse pharmacies. Key themes emerging from the interviews included motivation for providing the service, current practice frameworks, determinants for sustaining the service and future directions for the profession. Participants reflected on the professional satisfaction they derived from providing the service and being able to contribute to an important public health area. However, numerous impediments to service provision were discussed; these were broadly conceptualized as financial, professional, societal and geographical issues. Important practitioner needs were highlighted, including professional training opportunities and support. The need for a regulatory practice framework to ensure quality and uniformity of service provision within the profession was emphasized. Broader uptake of these services in the absence of such a framework was a key area of concern.
Conclusions: This study showcases a novel area of pharmacy service provision. Innovative services need to be explored and defined before being consolidated into professionally recognized areas of practice. For OSA services in Australia, the next key step for the profession is to establish a professional practice framework to support current and future implementers of the service and ensure a minimum standard of care.

Keywords: Professional pharmacy services; Public health; Obstructive sleep apnea; Novel services; Practice framework

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http://dx.doi.org/10.1016/j.sapharm.2014.08.009

Introduction

Modern pharmacy practice has undergone significant change, evolving from a predominantly medication supply role to a focus on clinical services.[1] More recently, further diversified roles have been identified for pharmacists, recognizing their broad health knowledge beyond the domain of pharmacotherapy. Newer practice frameworks are taking into consideration not only the skill set of the pharmacist, but the accessibility of pharmacy premises themselves.[2]

Within this landscape, pharmacies worldwide are exploring novel territory, for example, as key players in public health. A notable case in point is the involvement of some Australian pharmacies in the management of obstructive sleep apnea (OSA). OSA is a chronic sleep disorder, with prevalence estimates (of at least mild disease severity) ranging from 3 to 28% of adults in Western countries.[3] An estimated 80–90% of middle-aged adults with the condition remain undiagnosed.[4] Given the multiple comorbidities, and increased cardiovascular and mortality risks associated with OSA, there are considerable public health implications for undiagnosed and untreated disease.[5–8]

The management of OSA involves many interface points between the patient and the health care system. Community pharmacists are well placed to deliver aspects of OSA care, particularly screening and referral of 'at risk' patients. Their knowledge of medications, health conditions, and frequent interactions with the public provide ample opportunities for screening activities. There is also the potential for pharmacies to engage in a specialized capacity with aspects of care after diagnosis, such as the provision of continuous positive airway pressure (CPAP) devices. Nasal CPAP represents the mainstay of treatment for OSA.[9] Its use involves several key components, requiring the assistance and skill of a trained practitioner. The correct fitting of the mask is a crucial skill required by the CPAP provider, as this process is critical to patient acceptability and ensuring delivery of pressurized air to maintain upper airway patency.[10] While CPAP efficacy is high, patient adherence is problematic, and troubleshooting support, education, and counseling from providers are important factors in CPAP effectiveness.[11] Finally, ongoing adherence monitoring, equipment maintenance, and liaising with the referring physician are also aspects of CPAP provision. The authors previously surveyed Australian pharmacies involved in OSA care and found most practices centered around CPAP services.[12] However, a spectrum of other roles was evident. Fig. 1 depicts the known areas of pharmacy involvement across stages of OSA management.

OSA services within the pharmacy setting are still in their relative infancy in Australia. The impetus for pharmacy involvement has stemmed from a need to improve patient access to sleep services, due to supply-demand imbalances within the health care system.[13] Accessibility issues are further compounded by the increasing prevalence of OSA, which has paralleled the rise in obesity rates.[14,15] In Australia, strategies for addressing the burden of disease have included shifting aspects of OSA management from tertiary to primary care settings, and expansion of the sleep health workforce.[16–19] This has seen certain community pharmacies pioneer a role in providing OSA services. This represents an innovative area of pharmacy practice, from both a clinical and organizational perspective. Clinically, the service is unique in that it has a distinct public health emphasis and centers around a therapeutic device rather than a pharmaceutical product. Organizationally, the service model is novel in that it incorporates both the traditional supply role of pharmacists along with modern day practice concepts, such as forming a therapeutic alliance with the patient and accepting responsibility for patient health outcomes.[20,21]

The Australian pharmacy profession has yet to formally recognize or consolidate OSA services with the establishment of a professional practice framework, as has occurred with other expanded practice areas.[22,23] The diffusion of innovations model prescribes key factors for success in 'spreading' innovative practice: the need for understanding relative advantage, compatibility with existing values and practices, complexity, trialability, and evidence of outcomes.[24] In line with this, there is a need to explore current OSA services and establish a practice framework if they are to become a professionally recognized, sustainable area of pharmacy practice. It is also important to identify determinants for sustaining OSA programs, in order to support pharmacies providing, or contemplating providing, these services. To date, there has been little research investigating this novel area of practice, and there are no reports in the literature of pharmacists in other countries offering these services. While the authors have previously investigated OSA pharmacy services using survey format,[12,25] in-depth, qualitative studies describing the experiences and

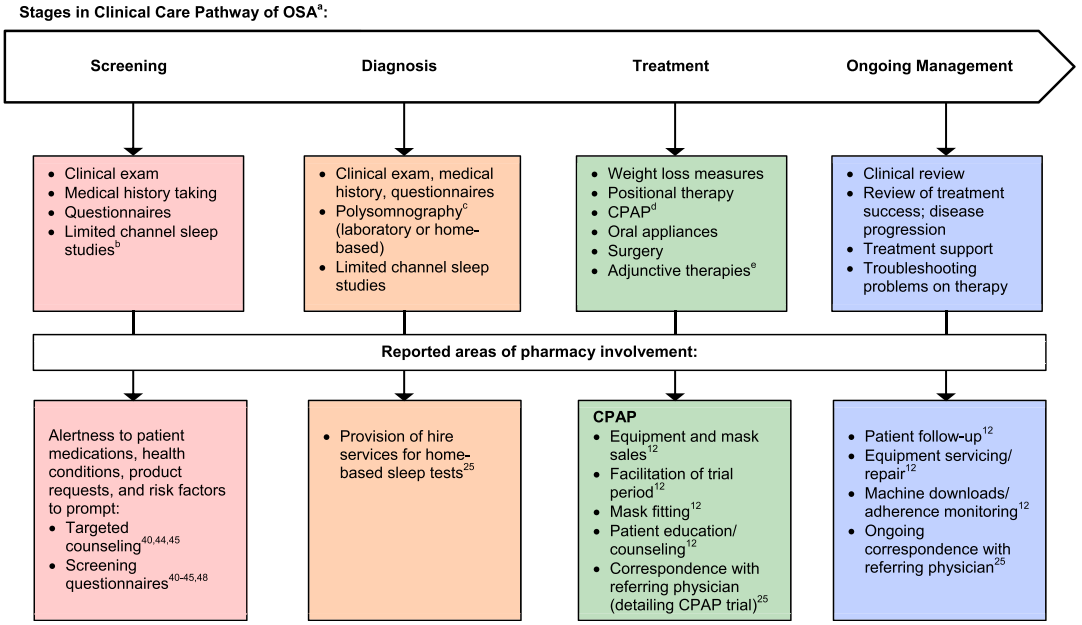

Fig. 1. Stages in clinical care pathway of obstructive sleep apnea and reported areas of pharmacy service provision. [a] OSA = obstructive sleep apnea. [b] A diagnostic test for OSA that measures fewer parameters than polysomnography. Oxygen saturation and respiratory airflow are usually measured, while sleep staging is generally omitted. May be used to 'rule in' OSA in high pre-test probability populations.[47] [c] An overnight, multi-parameter sleep test used in the diagnosis and evaluation of sleep disorders.[47] [d] CPAP = continuous positive airway pressure. [e] For example, bariatric surgery and pharmacologic agents.[46]

opinions of these practitioners are needed. Thus, the aim of this study was to explore the practices and perspectives of Australian pharmacy staff providing OSA services. Specifically the objectives were to examine issues related to the implementation of the service, sustaining the service, and future directions for the profession.

Method

Study design

A semi-structured interview format was utilized to provide a flexible, yet rich and targeted means of data collection. Telephone interviews were chosen to accommodate participation from interstate and regional pharmacies and allow diversity in participant demographics. Approval to conduct this study was obtained from the University of Sydney Human Research Ethics Committee (protocol 2012/2830).

Interview guide development

An interview guide was used to ensure consistency of data collection. Development of the interview guide was based on *a priori* areas for exploration, informed by previous survey findings.[12,25] Broadly, the interview guide focused initially on capturing the experiences of participants in implementing and sustaining OSA services, and progressed to future practice issues. This structure facilitated discussion of relatively straightforward aspects of service provision first, progressing to more cognitively challenging issues later in the interview. Prompts were used to explore issues in further detail if required. Fig. 2 presents a conceptual model of the research domains covered in the interview guide. To stimulate a detailed discussion of service configuration, the framework posed by Donabedian was used, whereby service quality is viewed within a 'structure-process-outcome' paradigm.[26] To further explore service provision outcomes, Kozma's Economic, Clinical, and Humanistic Outcomes (ECHO) model was adopted.[27] The research team reviewed and assessed the interview guide for face validity.

Recruitment process

Purposive sampling from a database of Australian pharmacies providing OSA services, compiled

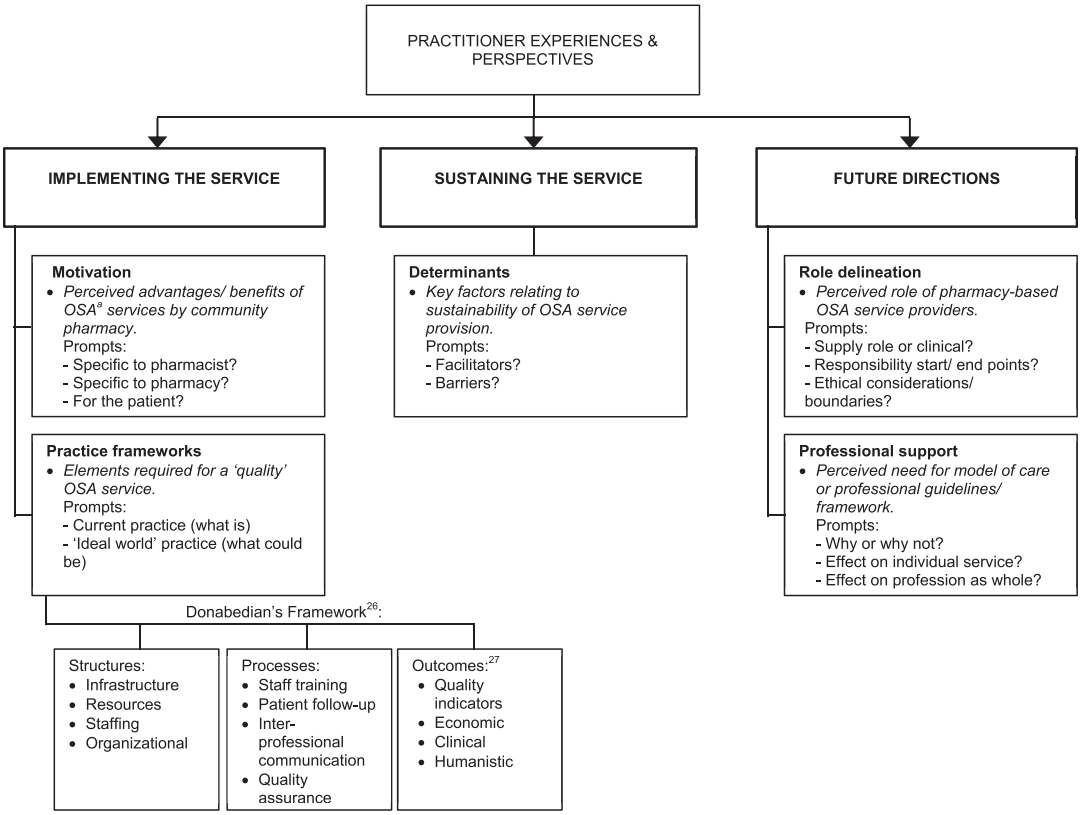

Fig. 2. Schematic representation of interview guide. [a] OSA = obstructive sleep apnea.

in an earlier study, was used for recruitment. Participants that had previously indicated interest in future OSA research projects were invited to participate first, however broader database listings were also used to obtain diversity in participant demographics. All participants were informed of the study via an E-mail invitation, which included a participant information sheet. Where the names of individuals were not known, invitations were addressed to the 'CPAP practitioner.' Participants were offered a $50 AUD department store gift voucher in recognition of their time to complete the study. Inclusion criteria required participants to be currently providing OSA-related services in a community pharmacy, have a minimum of 6 months experience providing these services, and be an employee or proprietor of a community pharmacy (i.e. not sub-contracted or employed by an external organization). Both pharmacist and non-pharmacist staff were eligible to participate. Invitees completed an online form if interested; these individuals were then contacted by telephone to organize an interview time. Consent was obtained from all participants prior to their interview; the consent form included a confidentiality statement and permission for the interview to be audio recorded. Demographic information was obtained from an online questionnaire, completed by participants prior to the interview. Participant recruitment continued until saturation of emergent themes was achieved (that is, when no further insight within the research framework occurred [see Fig. 2] and further sampling became redundant).[28]

Conduct of interviews

All interviews were conducted by the principal researcher (CH) between April and May 2013. Interviews were conducted both inside and outside business hours, depending on participant preference. All interviews were audio recorded using a digital device. The researcher also took detailed interview notes and made a summary of reflections at the conclusion of each interview. Throughout the interviews, the researcher

paraphrased key content back to participants to confirm their views were being accurately interpreted.

Data analysis

Interviews were transcribed verbatim with the exception of identifying characteristics (names and places were removed) to ensure participant confidentiality. Participants were offered the opportunity to review their transcript prior to its analysis to ensure accurate representation of their perspectives. No participants requested any amendments to their transcript. The researchers chose the framework approach[29] to analyze transcript data, given the study's specific *a priori* research domains.[30] After reading and re-reading all transcripts ('data immersion'),[29] the principal researcher undertook the primary data analysis. Transcripts were thematically coded using the analysis software QSR NVivo (QSR International Pty Ltd. Version 10, 2012). An experienced senior researcher (BS) conducted an independent analysis on a sample of 5 randomly selected transcripts and compared and validated the thematic analysis.

Results

Twenty-two interviews with pharmacy-based CPAP practitioners were conducted. The average duration of each interview was approximately 35 min (range: 24–51 min). Participant characteristics and the pharmacies they represented are described in Table 1. Participants were assigned a code during the de-identification of their transcript; these codes are included where direct quotations have been reported (e.g. 'P01').

Thematic analyses of the interview transcripts revealed 5 main themes and 12 sub-themes, derived inductively within the *a priori* domains for exploration.

Implementing the service

Table 2 summarizes the thematic analysis from this domain and presents selected participant quotations.

1. Motivation for providing sleep apnea services.

Altruism

Participants conveyed that their motivation for providing OSA services extended beyond, and in some cases with disregard to, commercial

Table 1
Participant and pharmacy characteristics

Variable	Sample, *n* (*n* = 22)
Participant characteristics	
Years of experience in providing CPAP[a]:	
0.5 to <5	9
5 to <10	8
10 to <20	5
Years of general pharmacy experience:	
0.5 to <5	5
5 to <10	2
10 to <20	3
≥20	12
Staff member type:	
Pharmacist	*(17)*
Manager/Pharmacist-in-charge	3
Partner	7
Sole proprietor	7
Non-pharmacist	*(5)*
Pharmacy assistant	1
CPAP nurse	3
Retail manager	1
Highest level of education:	
Secondary school/TAFE[b]	2
Bachelor's degree	17
Postgraduate degree	3
Pharmacy characteristics	
Location:	
Metropolitan	10
Regional	6
Rural or remote	6
State/Territory:	
New South Wales	8
Northern Territory	1
Queensland	2
Victoria	5
Western Australia	6
Brand:	
Chain or franchise	12
Independent	10
Type:	
Shopping center	8
Strip mall or isolated	12
Other	1
(Missing)	1
	Mean ± SD[c]
Hours of weekly operation	75 ± 28 (range: 48.5–168)
Number of CPAP consultations per week	19 ± 18 (range: 1–70)
Size of pharmacy in square meters	411 ± 246 (range: 120–1000)

[a] CPAP = continuous positive airway pressure.
[b] TAFE = technical and further education (Australian state government-funded institutions that provide vocational tertiary education courses).
[c] SD = standard deviation.

Table 2
Implementing the service: Summary of thematic analysis and selected participant quotations

Theme	Sub-theme	Selected participant quotations
1. Motivation for providing sleep apnea services.	*Altruism*	• "Um, and, yeah, you know, not having to sort of worry about self-interest and things like that because at the end of the day, you know, if nine out of ten patients out there aren't being treated, then there's something obviously not going right with the current model." (P10) • "… We're fairly remote in that, you know, we're, sort of, quite a long way from a major town… we're at least a hundred 'kay' *[100 km],* and, um, for people who have to, you know, have adjustments or they're trialing masks or something like that, it's a… big ask to drive a couple of hundred 'kays' in a day just to have, have something changed." (P01)
	Professional satisfaction	• "… with some people it's been day and night, the difference in their lives. We've saved people's lives… We're not trying to be pretend doctors, but it's quite amazing, ah, intervening in this area, the difference you can… you can make to people's lives." (P19) • "My primary outcome and the one that gives me the most pleasure, is the patient coming back and telling me how much their life has improved. Um, so, yeah, and you get absolutely wonderful stories of life improvement from a person who truly uses their machine properly and does the whole, um, scenario." (P13)
	Desire to differentiate	• "For pharmacy, um, it's very hard to find something that you can hang your hat on, that you can say, 'This is something of ours that we do well.' Because most pharmacies do a lot of very similar services and do it all very well. What's my point of difference to my competitors? You know, now we offer a CPAP service… fits those categories." (P11) • "… I don't think a lot of pharmacists have an idea about the level of commitment you need to run a successful model. It's not like testing someone's blood pressure or taking a blood glucose meter. It is a totally different mindset, um, and, um, you have to have a commitment to the model for it to work." (P16) • "… It is, is an area that is, it is, I don't like the word 'unique', but it is unique, ah, it is different from any other area within the pharmacy, um, it is not something that every pharmacy can choose to do… it is just something that does take a lot of time and… effort…" (P06)
2. Practice frameworks for provision of sleep apnea services.	*Restructuring of traditional pharmacy service model*	• "…People will come in, 'Oh, I want to get this looked at now.' You get adept at saying, 'Well, that's fine, but, you know, can we make an appointment?' And that works far better. In terms of staffing, because you just… it's quite complex… you've really got to have staff who know the machines and know it all inside out. And you just don't have six or seven of those on staff, you only have two or three …" (P11) • "We, we don't take them in off the street. We try not to, because it, it interrupts our workflow. We try and make appointments or time set aside so that we can give them the attention that they deserve and they can bring their sleeping partner along with them as well." (P03)

(*continued*)

Table 2 (*continued*)

Theme	Sub-theme	Selected participant quotations
		• "… People will expect to be able to come in at any time that's convenient for them, and I think we should move to a model that involves, um, being treated like a specialist … I think pharmacy has been at the beck and call of the public constantly, and I think we need to move away from that model to an appointment basis." (P19)
	Investment required to deliver a quality service	• "I mean it's a cost… you know, to set yourself up is costly; you've got a large inventory, you've got a big investment in staff, in equipment, in energy … " (P16) • "… It's only in the last two years that our level of referrals has gone up. It's like a critical mass or water going across the top of the dam. It takes a lot of time filling it up before you start to get the results." (P11)
	Acceptance of responsibility for patient health outcomes	• "They've all got different needs… we're not just trying to stop you snoring we're here to… increase your quality of your health…" (P09) • "For me the most important part would be the actual patient outcome… So, I mean, a patient needs to be both happy with the, with the actual treatment as well as you want to see them, you know, their health outcomes improve as well…" (P17) • "We'll also download the data, sometimes on a weekly basis, to see how they're doing… not what they say they're doing… And you can see improvements and that way… you can encourage them, 'You're doing so much better than you were three months ago.'"(P19)

interests. They perceived a community health need and an opportunity to contribute in this area. Undertones of pragmatism were also seen within this theme. Practical considerations for patients included the opportunity for continued patient interaction in pharmacies, and reduced waiting times compared with other venues.

The accessibility and convenience of the pharmacy premises was considered the overwhelming relative advantage for patients accessing OSA services in pharmacies. The expertise and experience of pharmacists was also recognized as an asset. Others reflected that it was this overall 'package' – the premises and the pharmacist – that made OSA services in the pharmacy setting beneficial for patients.

Professional satisfaction

Participants expressed that they found the provision of OSA services a rewarding area of professional practice. Some participants described dramatic differences in the quality of life of patients commencing CPAP therapy, and attached significance to the role they played in assisting these patients. Table 2 provides key participant quotations within this subtheme.

Desire to differentiate

Participants saw OSA services as an area that was specialized and allowed them to differentiate from other pharmacies. The OSA service model was frequently contrasted with everyday practice and other services within the pharmacy. Participants viewed that OSA services required a high standard of service provision. For this reason, there was a strong belief among some participants that OSA services were not suited to mainstream pharmacy practice, but should be reserved for those with a commitment to, and awareness of, the specialized nature of the service. Reference to the additional training and specialized skill set required to provide the service was also highlighted.

2. Practice frameworks for provision of sleep apnea services.

Restructuring of traditional pharmacy service model

Participants reflected on the significant reorganization of infrastructure and process workflow required to deliver a quality OSA service in the pharmacy. Particular emphasis was conveyed with regard to 'walk-in' versus appointment-based consultations. Most participants were able to accommodate 'simple' consultations on a walk-in basis, such as minor troubleshooting and spare part replacement, and recognized this flexibility as a distinct advantage for patients. However, for in-depth consultations, such as initiating a CPAP trial, the majority of participants favored an appointment system; the time and resource-intensive nature of the service were cited as reasons for this approach. Nonetheless, difficulties in overcoming patient expectations of the traditional pharmacy 'instant service' model were expressed.

Investment required to implement and deliver a quality service

Specific infrastructure investment described to operate the service included setting up a private consultation area, purchase of specialty equipment (including a range of CPAP machinery and masks), a bed or reclining chair, and an area for sterilization of hire equipment. Other areas of investment included staff training, hiring of additional staff, time delivering the service itself (both in initial consultations and patient follow-up), maintaining a wide range of stock, and allocation of existing infrastructure to the service. Many participants described, in particular, a significant *initial* investment and reflected that a return on investment was not usually realized until the service had matured.

Acceptance of responsibility for patient health outcomes

Most practitioners assumed a responsibility in assisting patients to achieve optimal health outcomes. They described the importance of in-depth patient education (of the disease state, lifestyle issues, and device operation), ongoing follow-up tailored to meet the patient's needs, and adherence monitoring and support. Adherence monitoring for CPAP was considered unique in that objective measures of usage were possible via device downloads or 'smart cards.' The quality of the CPAP service was often measured through such patient outcomes, in addition to other clinical and subjective measures of treatment success, and whether or not patients embraced long-term CPAP use after a trial period. Most participants regarded their responsibility to patients as ongoing, with support and follow-up services continuing beyond the CPAP trial period. However, not all participants offered ongoing management services or saw this as an area of professional responsibility (see Fig. 1).

Several participants remarked that the responsibility for outcomes was shared with the patient's physician, and highlighted the importance of working collaboratively to achieve the best possible health outcome for the patient. This role included communicating with the physician throughout the patient's CPAP trial period, joint troubleshooting, discussing proposed changes to therapy (and in some instances medications), reporting clinical parameters, referring patients back to their physician as appropriate, and for some participants, ongoing reports outlining adherence and patient review summaries.

Sustaining the service

Table 3 summarizes the thematic analysis from this domain and presents selected participant quotations.

3. Impediments to service provision.

Participants described numerous factors that posed an impediment to service provision and sustainability. These factors were conceptualized into the following sub-themes: *financial, professional, societal and geographical*. Key issues raised within each of these sub-themes are summarized in Fig. 3.

A significant impediment discussed by participants related to the advent of the 'discount' CPAP provider in recent years. Both pharmacy and non-pharmacy CPAP providers were discussed in this context.[e] The 'discount' concept encompassed not only aggressive pricing, but also the perceived philosophy towards patient care and service quality. Concerns were raised on two fronts: the threat to the financial viability of 'full service' providers, and patient safety issues. These concerns were particularly expressed with respect

[e] The CPAP industry in Australia is currently unregulated. A variety of supply channels are available, including tertiary clinics (public and private), private peripatetic consultants, Internet sites, direct manufacturer outlets, and numerous independent outlets, including community pharmacies. These services may not necessarily be operated by practitioners with a health care background or formal training.

Table 3
Sustaining the service: Summary of thematic analysis and selected participant quotations

Theme	Sub-theme	Selected participant quotations
3. Impediments to service provision.	*Financial*	• "… We don't really have a history in pharmacy of charging, you know, by the hour or by the appointment or anything like that… So we end up fixing the problems… that came from a person who just bought the first thing they found on the Internet, ah, or who wanted to sell at what is effectively our cost price, so, you know, providing hours of input for zero financial return." (P03) • "It's a lot of time and sometimes your remuneration is quite poor… It's hard to balance the remuneration with that time, because sometimes then they buy the CPAP machine elsewhere and then you're just left empty." (P14)
	Professional	• "… One of the big issues with CPAP delivery, I think, is the, the rise of the discount, of the Internet seller, who's providing machines to people without any service model at all." (P07) • "…Then it becomes a… a bargaining situation where one pharmacy has done all the work and they have provided this service at next to no charge… and then they go down the road and say, 'Oh, I can buy it from down the road at seventy dollars cheaper', and that person down the road hasn't put one minute into that person becoming, you know, um, providing a service to that person… yet then it starts into just a straight commercial transaction." (P06) • "… We meet with some, perhaps even some considerable, resistance from particular local GPs *[general practitioners]* but we've got enough support from others that we keep the service going and hopefully build a positive reputation of it." (P08)
	Societal	• "I think a lot of it is people aren't proactive with their health, and the same goes with sleep apnea. Some people don't see a doctor hardly ever. Some people can't be bothered." (P14) • "There should be a lot more awareness that sleep is a major, is a component of major chronic diseases… Sleep is currently not, um, regarded anywhere near as… an important risk factor as it should be… It should have a lot more focus than it does currently." (P13) • "I think there should be a little bit more government funding for it. A lot of people can't afford to be treated and they can't afford to purchase CPAP equipment because it is expensive. If they can't, they then go onto a fairly large waiting list for the public hospital and there's a vast amount of time that they're untreated." (P09)
	Geographical	• "… We have no one else, we're in a rural location, there's, there's no sleep clinic for *[name of town]*. It's a minimum two-hour drive and probably three or four of them before a patient gets tested and these patients shouldn't be driving anyway." (P03) • "I was in a remote location so, um, we were pioneering, really, and trying to overcome lots of challenges people have by living remotely. Like, they wouldn't otherwise have access to this sort of thing, without, you know, taking extensive time off work." (P14) • "… Now we're remote, so, um, we always keep maybe two *[CPAP machines]*, and if we do run out, we're looking at three weeks. So that's just a tricky remote thing." (P15)
4. Need to demonstrate quality service provision.		• "It does take time and you need to get their *[physician]* confidence. So, you need to be darn good at what you do so that the first time… And it might be two years before they ring you and say, 'Look, I've got this patient, what do you think?' … or you come back with a report sending it to the GP *[general practitioner]* stating it and they go, 'Wow, he knows his stuff,' and that's …You only get one chance at that… The first opportunity they have to ring you, you have to be… you have to be all over it, otherwise you lose their confidence and you won't get it back." (P02) • "… Sleep labs have to have confidence if they are referring to a pharmacy, that it is, that their, um, patient… is looked after properly… certainly it's about maintaining the professional reputation of pharmacy and it's also maintaining or, or, um, creating a good relationship with sleep labs and, and pharmacies." (P06)

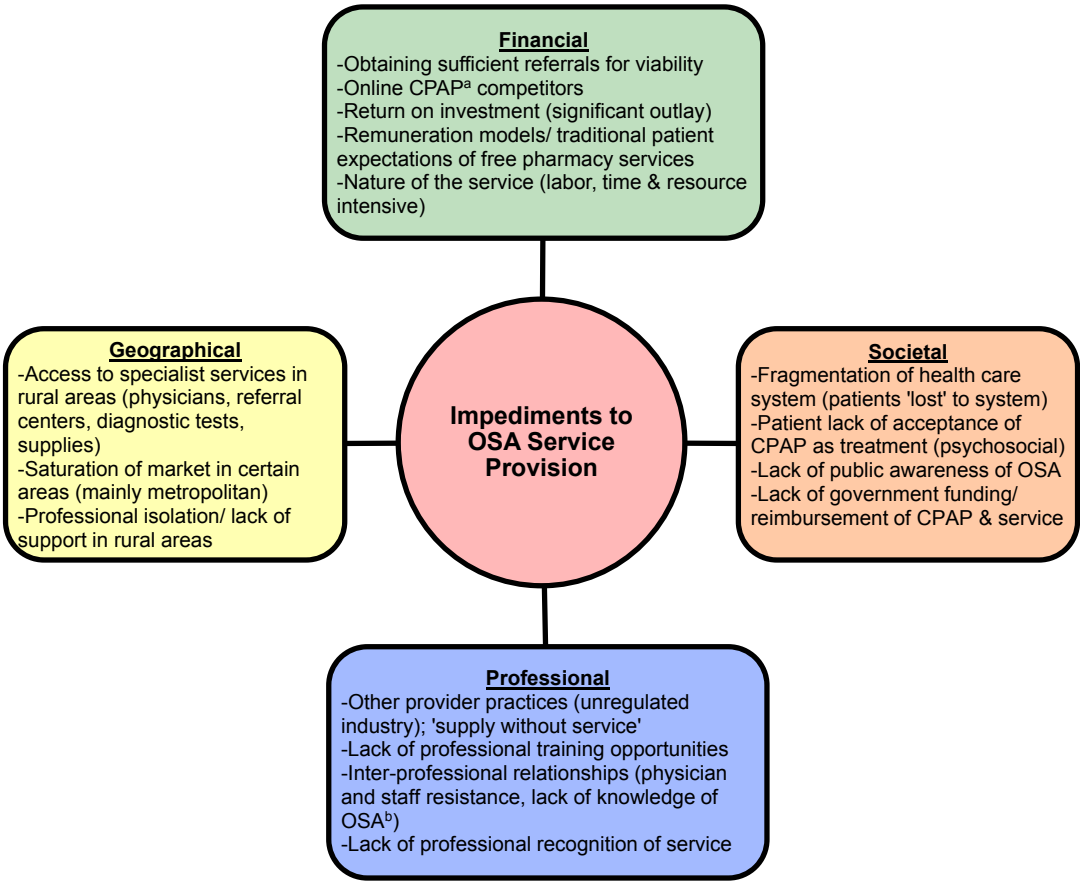

Fig. 3. Perceived impediments to obstructive sleep apnea service provision. [a] CPAP = continuous positive airway pressure; [b] OSA = obstructive sleep apnea.

to Internet-based CPAP providers. The majority of participants in this sample regarded themselves as providers of OSA clinical care, rather than solely as suppliers of CPAP devices. These participants viewed that practitioners who emphasized product sales over service were not providing true OSA care, and were potentially jeopardizing patient health outcomes. This lack of regulation within the CPAP industry was seen as a significant impediment.

4. Need to demonstrate quality service provision.

A key determinant for the sustainability of the service was the ability of pharmacy providers to demonstrate high quality service provision to referring physicians. The service was largely referral-dependent and 'successful' patient outcomes were deemed critical to establishing physician confidence and sustaining referrals. While participants described varying levels of communication based on individual physician preferences, it was generally acknowledged that providing written reports was an important component of demonstrating service quality. These reports most often detailed the results of a patient's CPAP trial, including clinical parameters since commencing treatment, and whether or not the patient had decided to continue with long-term therapy.

Future directions

Table 4 summarizes the thematic analysis from this domain and presents selected participant quotations.

5. Practitioner needs

Professional practice framework and role delineation

Table 4
Future directions: Summary of thematic analysis and selected participant quotations

Theme	Sub-theme	Selected participant quotations
5. Practitioner needs	*Professional practice framework and role delineation*	• "I think we have to have a more standard approach so that no matter where you go, to one of these pharmacies, that the minimum standard is always reached." (P02). • "… If there was a, a model, it would make it, um, oh, better for the patient. They'd get the same sort of thing, no matter where they went, um, and that can be an issue if they go into one place and they go into somewhere else, the different, different care they get." (P04) • "… We need access to that ongoing training and know where our boundaries are, because it's all a little bit gray. That's the problem. Where, where, … do we need to refer? You know, when, when, … do we need, ah, to send these people on to a, a sleep physician? There's got to be some, ah, guidelines for us to protect us." (P02) • "It can be, you know, sort of hard for you to know which parts need to… you need to have the doctor's say so for and which parts you can just do." (P04) • "… When I read some of the, ah, reports by sleep physicians about where they think the, um, the care process should lead, there's no pharmacist involved anywhere along their chain. I don't think they have any respect for us as providers of care in, … um sleep apnea. So, I think that would raise, you know, if we had a formalized system, it would certainly, ah, we would have higher esteem with them, ah, and, and with the general, you know, medical profession." (P07) • "… I have to say, you know this is probably going to become apparent in the, maybe, in the interview, the ethics of it, and I feel that's one of the issues that we are faced, in the way some people practice it… I guess the industry hasn't really found a way to …what's the word I'm looking for, regulate. It's, ah, very unregulated, and I think that's the ah, the main thing for pharmacy." (P21) • "Well, of course you have to maintain a certain standard if… the pharmacy has to maintain their, maintain their reputation as providing a, a professional service… apnea products in pharmacy have to be done properly, obviously it has to be done properly, it has to be done professionally." (P06) • "Well, I mean, we've got… guidelines for other services that we do provide… again, it's a complete care that we do provide… So, but standards, it just means that everyone's doing it uniformly and they've got enough knowledge and they're doing it the right way…" (P17)
	Professional training opportunities	• I would love someone to come out with a course that's specifically for pharmacists or for it to be integrated into the pharmacy schools… at the very least, there, there needs to be a deliverer of training that's separate from, um, from the manufacturers." (P07) • "… It'd be really good … if the specialists themselves, um, were able to, you know, provide… some kind of, you know, training, that… they'd recognize… They [CPAP manufacturers] obviously have a very, very good knowledge… I just think that they're just trying to really just peddle their products… It's sort of more product-based rather than sort of being, you know, condition based I guess." (P10) • "… Current training… I'm just talking about the manufacturer one I got done, um, so it's… I mean, yeah, it's completely inadequate at the moment. And um, a lot of it I just got from asking a lot of questions and annoying a lot of people, really." (P14) • "… Some manufacturers are very thorough with their training, um, I, I think the more training the better, and if there were other options that, that, um, staff and pharmacists could, could use as well as the manufacturers' training, that would be, that would be good…" (P06)

The need for a professional model of care or practice framework to guide current and future services was expressed by the vast majority of participants. Numerous reasons were given as to why a practice framework was necessary or would prove beneficial. These included: establishing consistency in service quality and ensuring minimum standards of care (to protect *patients*); delineating professional roles and establishing practice boundaries (to protect *pharmacies*); and giving credibility to services and upholding the reputation of pharmacies as providers of quality services (to protect the *profession*).

Participants viewed that a professional framework could support future providers of OSA services. They described the challenges they had faced in implementing the service in the absence of a framework or professional support network, using phrases such as *'ad hoc,' 'trial and error,'* and *'learning on my feet'* to describe their experiences.

A practice framework was needed not only to address clinical issues, such as when referrals to specialist physicians were required, but also ethical considerations. The primary area requiring role delineation, from an ethical standpoint, related to pharmacies that provided both diagnostic and treatment services (i.e. home-based sleep tests and provision of CPAP devices; see Fig. 1). Participant views varied considerably on this issue, with some perceiving no conflict of interest in offering both services, others acknowledging that there was the potential for conflicts of interest but that these could be managed and overcome, and others perceiving a blatant conflict of interest and expressing disapproval of pharmacies providing both services. For those that viewed this issue as being 'manageable', it was generally acknowledged that protocols needed to be in place governing the conditions for recommending tests that could lead to diagnoses and initiating treatment services, and that in the absence of such a framework, there was potential for both real and perceived conflicts of interest.

Participants expressed concern over the unregulated nature of the CPAP industry and the practices of other providers. Fears related to the direction the industry was headed, and in CPAP becoming a commodity, were conveyed. There was a general consensus that a practice framework would, to an extent, help regulate practice and preserve a service ethic, at least within the pharmacy profession if not outside. Participants commented that if a framework were to be developed, it needed to be pragmatic and involve key stakeholder input from both the pharmacy and medical professions.

Professional training opportunities

A significant issue raised by the majority of participants was the lack of professional training options available. The vast majority of participants had received their training from CPAP manufacturers and/or self-directed study. While manufacturer training was considered important and regarded well by some participants, particularly for device-specific technical aspects, professionally developed courses were desired. Participants recognized that an inherent bias existed with manufacturer-delivered training, and felt that professionally developed courses would lend them more credibility within the medical community as providers of OSA care. Some participants envisaged that a professional practice framework would encompass or stipulate minimum training standards.

Discussion

This is the first study to explore in-depth the experiences and practices of Australian pharmacy practitioners involved in OSA services. This study showcases a novel professional service and highlights the need for professional support to consolidate innovative practices into recognized pharmacy service areas. The descriptions of patient-centered service models from participants suggest OSA services align with professional practice principles and these services are worth sustaining. The use of Donabedian's framework assisted with the characterization of these services and in identifying factors for implementation and sustainable service provision. These are important areas for consideration by the profession and the wider industry. The preliminary framework outlined in this study provides a point of reference for current and future providers of these services, and for the pharmacy profession in defining best practice models.

The defining of new services is important for successful implementation. Once a new service has been defined, there is then the opportunity for it to be refined and measured. OSA services represent a unique case when trying to define their place within existing pharmacy practice paradigms. The concepts of pharmaceutical care,[20] cognitive pharmaceutical services,[31] disease state management services,[32] or the newer 'professional

pharmacy services'[33] offer definitions or philosophical molds for the provision of pharmacy services. OSA services encompass elements of all these definitions while still fitting a niche in the practice arena by incorporating specialized technical skills in addition to the emphasis placed on patient outcomes. While the profession has yet to formally define the role of pharmacy in providing OSA services, participants in this study viewed themselves as providers of clinical, patient-centered care. Thus, the profession should be encouraged to consider and define these services in this light rather than as purely a supply role.

Although OSA services in the pharmacy setting remain a relatively specialized field at present, there has been a growth in the number of new service providers in recent years, from both within and outside the pharmacy profession. According to Rogers' diffusion of innovations theory, the pharmacy profession could be seen to be transitioning between the 'innovators' and 'early adopters' stages.[24] The profession has thus reached a critical point where this service model needs to be formally defined and supported with a practice framework or guidelines. Further 'diffusion' of this innovation in the absence of such a framework could promote the development of substandard service models. Indeed, in keeping with Rogers' theory, 'innovators' tend to exert great time and energy in developing new services, whereas 'early adopters' often reinvent and simplify innovations to suit more mainstream needs.[34] Many participants in this study spoke of the complex and specialized nature of the service, and the time required developing new skills and understanding the disease state. The perceived complexity of an innovation is a deterrent for rapid adoption, which could explain, in part, the emergence of oversimplified OSA models that are attracting more rapid rates of adoption. While reinvention and continuous improvement are necessary components for service sustainability, it is important that attempts to 'simplify' OSA services are not at the expense of service quality.

In addition to complexity, other components within Rogers' model for determining the success of an innovation include the perceived relative advantage of the service and compatibility with existing values and practices.[24] Participants described professional satisfaction and a point of differentiation from other professional services as distinct advantages of OSA service provision. The patient-centered, clinical care emphasis of the service described by many participants could be seen as being consistent with existing professional values and pharmacy practice. Additional components that determine success are trialability, and evidence of outcomes.[24] Mapping the experiences and practices of these participants provides a template and reduces uncertainty for those contemplating future service provision. A descriptive framework may also stimulate peer discussion and assist with identifying areas for practice improvement. An understanding of all of the above issues is important for the advancement of OSA services in pharmacies.

Expanded professional service areas have been proposed as a way forward in ensuring the viability of Australian community pharmacies, who face growing economic uncertainty.[2,35] Singleton and Nissen have suggested that the Australian community pharmacy industry is experiencing conditions of hypercompetition.[36] In this environment, pharmacies increasingly need to find new service areas to differentiate themselves. Indeed, participants in this study conveyed that a desire to differentiate was a motivating factor in providing OSA services. However, it is important that in grasping at innovation, pharmacies uphold the profession's reputation as deliverers of quality services. This was an important point highlighted by participants themselves.

The need to delineate the role of pharmacy within an interdisciplinary sleep health team was a key theme raised in this study. The variability observed in practice models, particularly with regard to pharmacies that offer both diagnostic and treatment services, has attracted concerns from the medical community.[37] In seeking to address issues relating to the undiagnosed population and access to diagnostic services, there has been a blurring of boundaries for pharmacies that provide screening, diagnostic *and* treatment services. In an unregulated environment, this is particularly concerning for the profession, as there is no mechanism for ensuring patient best interests and safety are not compromised. There is a need for dialog between the pharmacy and medical professions to define boundaries that will safeguard both patients and pharmacies alike.

Study limitations

While the study did not aim for generalizability of findings, the recruitment method may have introduced sampling bias. The views of these participants may not be representative of other

pharmacy practitioners. It is likely that this sample contained a high proportion of 'innovators' who felt passionately about upholding a service ethic within this professional area. However, in seeking to define a practice framework, it could be argued that providers at the higher end of the service quality spectrum are the subjects of interest. As all interviews were conducted by telephone, non-verbal cues could not be identified, however paraphrasing and participant review of transcripts were used to strengthen the credibility of the findings.

Future directions

Participants in this study expressed significant concern over the direction they felt the profession and, in particular, the CPAP industry at large was headed. The substandard practices of other providers were viewed as a key impediment to service sustainability. These practices may be in part attributed to the unregulated nature of the CPAP industry in Australia. While the pharmacy profession may not be able to regulate the practices of other OSA service providers, there is a need to establish a best practice framework within the profession. As health care professionals bound by professional codes of conduct,[38,39] pharmacists need to distinguish themselves as providers of quality sleep services within the industry; the pharmacy profession should be at the forefront of establishing quality care standards for OSA service provision.

Conclusions

Australian pharmacists have been innovative in undertaking OSA services. The next key step for the profession in Australia is to consolidate these services with the development of a professional practice framework or professional guidelines. A formal definition of pharmacy's role in this area and the boundaries of service provision and responsibility are required. This case study exemplifies the need for pharmacies exploring novel services to be supported by the profession to ensure service quality and sustainability.

Acknowledgments

The authors would like to thank all participants who took part in this study and contributed their time and opinions. CH is the recipient of scholarships from the Australian Postgraduate Award (APA) and the NHMRC Center for Integrated Research and Understanding of Sleep (CIRUS), and gratefully acknowledges this support.

Funding: This research received funding support from the National Health and Medical Research Council Center for Integrated Research and Understanding of Sleep (CIRUS). The funding source did not have a role in the study design; the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Conflicts of interest: The authors declare no potential conflicts of interest with respect to the research or authorship of this document.

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